
Moving beyond surrogate endpoints in cell therapy trials for heart disease.

Journal: Stem Cells Transl Med

Publication Year: 2014

Authors: Konstantinos Malliaras, Eduardo Marban

PubMed link: 24292794

Funding Grants: Mechanism of heart regeneration by cardiosphere-derived cells

Public Summary:

Cell therapy for heart disease began clinically more than a decade ago. Since then, numerous trials have been performed, but the studies have been underpowered, focusing primarily on low-risk patients with a recent myocardial infarction. Many data have accumulated on surrogate endpoints such as ejection fraction, but few clinical conclusions can be drawn from such studies. We argue here that the time is right for targeting larger and/or higher-risk populations for whom there is some expectation of being able to influence mortality or rehospitalization.

Scientific Abstract:

Cell therapy for heart disease began clinically more than a decade ago. Since then, numerous trials have been performed, but the studies have been underpowered, focusing primarily on low-risk patients with a recent myocardial infarction. Many data have accumulated on surrogate endpoints such as ejection fraction, but few clinical conclusions can be drawn from such studies. We argue here that the time is right for targeting larger and/or higher-risk populations for whom there is some expectation of being able to influence mortality or rehospitalization.

Source URL: <https://www.cirm.ca.gov/about-cirm/publications/moving-beyond-surrogate-endpoints-cell-therapy-trials-heart-disease>